

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1, 3-6 and 8-20 are currently pending in the application, with claim 1 being the independent claim.

II. The Rejection Under 35 U.S.C. § 102(b)

The Office Action, at pages 2-5, maintains the rejection of claims 1, 3 and 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by Alexander *et al.* (EP 0691079 A2; 1996) (“Alexander”) in light of Brenna JT (“Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man”, *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only) (“Brenna”). Although it acknowledges that Alexander fails to teach eicosapentaenoic acid and/or docosahexaenoic acid, the Office Action relies on the disclosure of Brenna, for the teachings that α -linolenic acid is an omega-3 fatty acid precursor that is converted into eicosapentaenoic acid and docosahexaenoic acid, and infers from these teachings that administration of plant oils containing α -linolenic acid necessarily contains eicosapentaenoic acid and docosahexaenoic acid, because α -linolenic acid will be converted to either or both of these products, *absent factual evidence to the contrary*. Applicant respectfully traverses this ground of rejection.

Claim 1 of the present application relates to a method for supplementing the diet of a subject with diabetes mellitus comprising administering a *composition* containing a fat phase, comprising *eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides*. Alexander fails to disclose several essential elements of the claimed invention. First, Alexander fails to disclose eicosapentaen acid and/or docosahexaen acid as multiple

unsaturated triglycerides. Second, the α -linolenic acid disclosed in Alexander must be metabolized inside the stomach of the patient in order to be converted into eicosapentaen acid and/or docosahexaen acid. The Federal Circuit recently clarified the definition of "medicinal preparations" in *Novartis Pharm. v. Eon Labs*, 363 F.3d 1306 (Fed. Cir. 2004). Specifically, the court held:

a "medicinal preparation" is a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body.

Id. Further, the Federal Circuit clarified issues particularly relevant to this application, as follows:

Medical dictionaries define "preparation" in terms of a substance that is made prior to being administered. *See Merriam Webster* (defining preparation as "something that is prepared; *specifically*: a medicinal substance made ready for use); *Dorland's* at 1502" (defining "preparation" as "a medicine made ready for use"); *Stedman's* at 1440 (defining "preparation" as "[s]omething made ready, as a medicinal or other mixture, or a histologic specimen"). Thus, contrary to the suggestion in the dissent, *post* at 1314, a "medicinal preparation" is a preexisting product that is administered to treat disease and therefore must necessarily be prepared outside the body.

Id. Contrary to the teachings of Alexander, the method of the present application requires the administration of a *composition*. The composition of the claimed invention is prepared outside the body (*see* paragraphs [0042]-[0045] at page 13 of the specification). Therefore, *even arguendo*, that the α -linolenic acid disclosed in Alexander would convert into metabolite products formed within the stomach of a patient after ingestion, Alexander still fails to disclose a composition, *i.e.*, a composition that is prepared outside the body, comprising eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides, as claimed in the present application.

Moreover, the specification at paragraph [0017] on page 6 of the present application clearly teaches that there is a big difference between applying a precursor of a particular compound to a patient and administration of the compound as such. In fact, only 2 to 7% of the linoleic acid introduced with plant oils is converted into the long chain omega-3 fatty acid (C20:50 and C22:6). Therefore, even if all of the α -linolenic acid disclosed in Alexander would convert into metabolite products formed within the stomach of a patient after ingestion, Alexander would still fail to disclose a composition comprising eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides *in an amount sufficient to regulate and normalize fat metabolism in the patient being treated*, as claimed in the present application.

At least for the reasons stated above, the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

III. The Rejections Under 35 U.S.C. § 103(a)

A. The Rejection of Claims 1, 3, 6, 9 and 11-19

The Office Action, at pages 5-8, maintains the rejection of claims 1, 3, 6, 9 and 11-19 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only) ("Brenna"), in view of U.S. Patent No. 3,995,069 to Harries. Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3 and 6 is demonstrated above. Harries does not remedy the deficiencies of Alexander and Brenna. Rather, Harries discloses emulsifier blends. Thus, Harries, like Alexander and Brenna, fails to disclose or suggest the claimed invention.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The Rejection of Claims 1, 3-6, 8-10 and 20

The Office Action, at pages 8-11, maintains the rejection of claims 1, 3-6, 8-10 and 20 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) (“Alexander”) in light of Brenna JT (“Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man”, *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only) (“Brenna”), in view of Madigan *et al.* (“Dietary Unsaturated Fatty Acids in Type 2 Diabetes”, *Diabetes Care* 23:1472-1477; 2000) (“Madigan”), Heine *et al.* (“Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients”, *Am J Clin Nutr*, 49(3):448-456; 1989, Abstract Only) (“Heine”) and the Merck Index (“Citric Acid”, Monograph 2328, 1989; page 363). Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3, 6, 9 and 11-19 is demonstrated above. The additional references, Madigan, Heine and the Merck Index, do not remedy the deficiencies of Alexander and Brenna, as none of these references discloses nutritional compositions comprising eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides.

The Office Action alleges that the artisan skilled in the art, in view of the teachings of the prior art, would have been motivated to use linoleic acid as further ingredient for the treatment of diabetes mellitus. In particular, with regard to the teachings of the prior art, the Office Action contends the following:

Applicant is first reminded that Madigan discloses a linoleic-enriched diet as “not the best option” (emphasis added) for people

with type 2 diabetes. *Though this may be a non-preferred manner for treating diabetic patients due to the fact that it does not provide a particularly effective means of glycemic control*, Applicant is reminded that (1) a preferred embodiment (in this case *an oleic acid-rich diet*) does not constitute a teaching away from a non-preferred embodiment (in this case *a linoleic acid-rich diet*) and Heine clearly supports the conclusion that *despite its lack of effect in providing glycemic control and/or carbohydrate tolerance*, use of a linoleic acid-enriched diet in a diabetic patient does, in fact, provide at least some reduction in the atherogenic lipoprotein profile.

Office Action at pages 9-10 (emphasis added, internal citations omitted).

The cited references, however, do not stand for such a proposition. The Office Action's allegations are wrong, because its characterization of the teachings of the cited references is factually erroneous. In fact, Madigan teaches:

The results of our study suggest that *a linoleic acid diet may not be the best option for people with type 2 diabetes*. In this study *a linoleic acid-rich diet was associated with increased fasting insulin and glucose levels, increased postprandial and LDL cholesterol level, all of which are associated with atherosclerosis risk*. In conclusion, an oleic acid-rich diet appears to be a more suitable option for type 2 diabetic patients.

Madigan at page 1476 (emphasis added). The statement in Madigan that linoleic acid diet may not be the best option for people with type 2 diabetes **actually means** that linoleic acid is totally *unsuitable* for the treatment of type 2 diabetes. In fact, based on the reported study, Madigan concludes: *"This study suggests that, in type 2 diabetes, an oleic acid-rich Mediterranean type diet versus a linoleic acid-rich diet may reduce the risk of arterosclerosis by decreasing the number of chylomicron remnant particles"* (see "Conclusions" on page 1472).

Clearly, since Madigan states that a linoleic acid diet is associated with increased insulin and glucose level as well as an increased postprandial and LDL-cholesterol level, all of which are associated with arterosclerosis risk, the artisan skilled in the art would not be motivated to

supplement the diet of a diabetic patient with linoleic acid! Therefore, it is apparent that the Office Action has totally misrepresented the teachings of Madigan, as Madigan undoubtedly teaches away from supplementing the diet of a diabetic patient with linoleic acid. Accordingly, the teachings of Madigan, even in combination with Alexander and Brenna, fail to teach or suggest the claimed invention.

Similarly, although Heine discloses that a linoleic-enriched diet in patients with NIDD causes a less atherogenic lipoprotein profile than a diet with a low polyunsaturated to saturated fat ratio, the reference clearly teaches that linoleic acid does not show a positive effect on glycemic control and carbohydrate tolerance. Accordingly, Heine, even in combination with Alexander, Brenna and Madigan, fails to teach or suggest that linoleic acid has positive effects with regard to treatment of diabetes mellitus.

Therefore, for at least the reasons stated above, the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date May 15, 2008

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